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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,498	08/14/2006	Colin G. Caro	DEHN 2 00008	7739
27885	7590	06/16/2009		
Fay Sharpe LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115				
EXAMINER				
WOLF, MEGAN YARNALL				
ART UNIT		PAPER NUMBER		
3738				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/549,498

**Applicant(s)**

CARO ET AL.

**Examiner**

Megan Wolf

**Art Unit**

3738

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 8, 9, 12, 13 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9, 12, 13 and 28-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/08 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 11/11/08 have been considered but are moot in view of the new ground(s) of rejection.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-3, 8, 9, 12, 13, 28-31, and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/549211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only differ in terminology and intended use. The claims in both applications includes a tubular portion substantially free of ribs or grooves, wherein the center line of the lumen follows a helical path with a helix angle less than or equal to 15° and the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion. The dependent claims are identical aside from the preamble which includes intended use of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 8, 9, 12, 13, and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the centre line" in line 3, "the amplitude" in line 5, "the helix" in line 5, and "the internal diameter" in lines 5-6. There is insufficient antecedent basis for these limitations in the claim.

Claim 2 recites the limitation "the amplitude" in line 1, "the helical centre line" in lines 1-2, "the internal diameter" in line 2, and "the tubing" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the centre line" in line 3, "the amplitude" in line 5, "the helical centre line" in line 5, and "the internal diameter" in lines 4-5, "the amplitude" in line 5, and "the helical centre line" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the centre line" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 recites the limitation "the centre line" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation "the amplitude of the helical centre line" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the amplitude of the helical centre line" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "the helix angle" in line 1 and "the helical centre line" in line 2. There is insufficient antecedent basis for these limitations in the claim.

Claim 37 recites the limitation "the centerline" in line 4, "the amplitude" in line 6, "the helix" in line 6, and "the internal diameter" in line 6. There is insufficient antecedent basis for these limitations in the claim.

Claim 40 recites the limitation "the helix angle of the helical winding" in lines 1-2, and "the helical centre line" in line 2. There is insufficient antecedent basis for these limitations in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 8, 9, 28, 29, 32, 33, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Cymbalisty 6,896,007. Cymbalisty discloses a graft (considered a tube) comprising flow tubing having a tubing portion defining a substantially circular flow lumen, wherein the graft is set such that the center line of the flow lumen follows a substantially helical path (fig.2) with a helix angle less than or equal to 15° (helix angle =  $\tan^{-1} (D/P) = 11.3^\circ$ ; see fig.3 where  $P=5D$ ), the amplitude of the helical centre line is less than or equal to one half of the internal diameter of the tubing portion, and wherein the amplitude of the helical centre line divided by the internal diameter of the tubing portion

is at least 0.05 (see shaded regions of figs. 1 and 3 which show the line of sight which yields the relative dimensions as claimed).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 8, 9, 12, 28-30, 32-34, 37, and 38, are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisky 6,896,007.

Re claims 1-3, 8, 28, and 37, Caro discloses the invention substantially as claimed including a graft comprising flow tubing having a tubing portion defining a flow lumen, the flow lumen being substantially free of ribs or grooves, wherein the graft is set such that the center line of the flow lumen follows a substantially helical path (col.3, ll.50-55). However, Caro does not disclose that the centerline of the flow lumen has a helix angle of less than or equal to 45° and the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion wherein the amplitude of the helical center line divided by the internal diameter of the tubing is a least 5%.

Cymbalisky teaches flow tubing, in the analogous art of conduits, wherein the tubing is set such that the center line of the flow lumen follows a substantially helical path with a helix angle of 11.3° and an amplitude of the helix less than or equal to one half of the internal diameter of the tubing portion wherein the amplitude of the helical center line divided by the internal diameter of the tubing is a least 5% for the purpose of

creating dynamic mixing of its flowing contents (col.2, ll.41-44) which prevents deposition of solids along the base of the conduit (col.4, ll.1-2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the generic helical formation of the graft of Caro in view of the specific dimensions taught by Cymbalistry in order to provide flow tubing that creates swirl flow and prevents blockages with the interior of the graft. The open channel shown in Cymbalistry is also effective to provide a conduit for blood even if blockages due form along the tubing walls.

Re claims 9 and 29, the cross section of the tubing of both Caro and Cymbalistry is substantially circular (figs. 5 and 2 respectively).

Re claims 12 and 30, see Caro fig.6.

Re claims 32 and 33, see Caro col.3, ll.58-61.

Re claims 34 and 38, Caro teaches that the graft is formed of known suitable biocompatible material (col.3, ll.55-58) and that the graft maintains its shape prior to implantation (clm.1). The process by which the device is made, including thermosetting, is not germane to the issue of patentability of the device itself.

11. Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalistry 6,896,007 as applied to claims 1 and 3 above, and further in view of Healy et al. 5,670,161. Caro in view of Cymbalistry discloses the invention substantially as claimed, but does not disclose a graft comprising a pharmaceutical coating.



Healy discloses a stent graft, in the same field of endeavor, comprising a drug coating for the purpose of positively affecting healing at the site of implantation (col.10, ll.10-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutical coating to the graft of Caro in view of Cymbalisty in order to induce healing at the site of implantation, as taught by Healy, col.10, ll.10-13. It is well known in the art to coat a graft with pharmaceuticals to prevent thrombosis, etc.

12. Claims 35, 36, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro 6,039,754 in view of Cymbalisty 6,896,007 as applied to claims 1 and 37 above, and further in view of Angelini GB 2298577 (submitted in IDS). Caro in view of Cymbalisty discloses the invention substantially as claimed and as discussed above. Caro further discloses that in order to maintain the tubing open a stent or other structural support may be used internally, externally, or integral with the wall of the tubing (col.3, ll.58-61). However, Caro in view of Cymbalisty does not specifically disclose that the external support may be in the form of a helical winding wherein the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen.

Angelini teaches a graft, in the same field of endeavor, wherein a stent with a large helical angle (as discussed in the current application par.69) is used around a graft for the purpose of providing beneficial effects on the luminal size, the degree of medial and intimal thickening, and cell proliferation (pg.2, ll.11-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the graft of Caro in view of Cymbalista to include the external helical winding taught by Angelini in order to help maintain the circular cross-section of the tubing. As Angelini discloses a helix angle of the helical winding to be close to 90°, the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen of the device as modified.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738